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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/885,188	06/21/2001	Chris Somerville	PW 280903/20263	7811
9629	7590	04/23/2004	EXAMINER	
MORGAN LEWIS & BOCKIUS LLP 1111 PENNSYLVANIA AVENUE NW WASHINGTON, DC 20004			MCELWAIN, ELIZABETH F	
			ART UNIT	PAPER NUMBER
			1638	

DATE MAILED: 04/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/885,188

Applicant(s)

SOMERVILLE ET AL.

Examiner

Elizabeth F. McElwain

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 37-41 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 37-41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

The amendment filed January 26, 2004 has been entered.

Claims 22, 23, 27 and 31-36 have been cancelled.

Claims 37-41 are newly submitted.

In view of Applicant's previous election of Group IV, drawn to Canola oil, in Paper No. 14 the present claims are examined to the extent the claims are drawn to Canola oil, which would be derived from the plant species *Brassica napus*.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The statement that the claims are free of the prior art is withdrawn in view of the art rejection set forth below.

Specification

The objection to the disclosure is withdrawn in view of the amendment of the specification.

Drawings

The objection to the drawings is withdrawn in view of applicant's response

Claim Objections

Claims 40 and 41 are objected to because of the following informalities: the claims recite non-elected plant species. Appropriate correction is required.

Claim Rejections - 35 USC § 112

Claims 37-41 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record set forth in the last office action for claims 22, 23, 27, 31-33 and 35-36.

Applicants' arguments filed January 26, 2004 have been fully considered but they are not persuasive.

Applicants assert that every claimed embodiment does not have to be present as an example and that the characteristics of the claimed oil are described in sufficient detail such that a person having ordinary skill in the art would recognize that Applicants were in possession of the claimed invention at the time of filing. Applicants' further state that the level of the hydroxylated fatty acids in the non-transformed plant is irrelevant that what is required is that the claimed oil have an increased level, and this can be determined by making a direct comparison of the two samples and an example of this analysis is provided in the specification. In addition, applicants argue that it is irrelevant what the level of each hydroxylated fatty acid would be in oils from other plant species, since all that is required is that the level of hydroxylated fatty acids is increased and that this determination is a simple matter and an example is provided in the specification.

Furthermore, applicants assert that other characteristics of the claimed oil may or may not have are not relevant. Applicant argues that a person skilled in the art can distinguish the claimed triglyceride oil because it has an increased hydroxylated fatty acid content compared to a triglyceride oil obtained from seeds of the same plant species that does not have the DNA construct using the methodology set forth in the specification. Applicants also assert that the example provided of transformed *Arabidopsis* plants is accepted as a model for higher plants, including closely related species, such as *Brassica* and *Crambe*, and there is no requirement for every embodiment to be exemplified in a patent application.

The Examiner maintains that the rejection is proper for the reasons of record set forth in the last office action. The claimed triglyceride oils have only been described in comparison to oil that could be isolated from the seeds of the same plant species that has not been transformed with a kappa hydroxylase gene. However, while one skilled in the art would be able to compare the seed oil of a transformed plant with the seed oil of a non-transformed plant of the same species, one skilled in the art does not have a sufficient description of the claimed oil to differentiate said oil from any other oil that is not part of such a side-by-side comparison. Applicants are claiming the triglyceride oil by the method by which it is made, but not by any characteristics that distinguish the claimed oil from any other oil that comprises hydroxy fatty acids.

Furthermore, one example of oil that is derived from transformed seeds of *Arabidopsis* does not define or describe oil that would be derived from any other plant species, given that each plant species differs in the particular combination and expression patterns of oil

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biosynthetic genes. One cannot ascertain from the chemical composition of oil from the transformed *Arabidopsis* what the chemical composition of oil would be from any other plant species transformed with a kappa hydroxylase gene or even if any hydroxy fatty acids would be produced in other plant species. In fact, while the example of transformed *Arabidopsis* indicates that *Arabidopsis* can produce hydroxylated fatty acids, one cannot identify a specific chemical composition of oil for *Arabidopsis* transformants given that different transformants of *Arabidopsis* will have different levels of expression of the kappa hydroxylase gene, and therefore different compositions of the oil extracted from each. The fact that a plant has been transformed with a kappa hydroxylase gene does not provide a written description of the oil that may be extracted from the seeds of said transformed plant.

Claims 37-41 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a triglyceride oil obtained from *Arabidopsis* that has been transformed with a nucleic acid sequence encoding a fatty acid hydroxylase, which comprises ricinoleic, lesquerolic, densipolic, and auricolic acid, does not reasonably provide enablement for triglyceride oil from a plant that has been transformed with a nucleic acid sequence that encodes a fatty acid hydroxylase, including from a Canola plant, wherein said oil has a hydroxylated fatty acid content that is increased compared to the hydroxylated fatty acid content from an oil obtained from seeds of the same plant that has not been transformed with a nucleic acid sequence that encodes a fatty acid hydroxylase. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to

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make and/or use the invention commensurate in scope with these claims, as stated in the last office action for claims 22, 23, 27, 31-33 and 35-36.

Applicants' arguments filed January 26, 2004 have been fully considered but they are not persuasive.

Applicants assert that they have provided an example of transforming *Arabidopsis* with a kappa hydroxylase gene to produce a triglyceride oil containing hydroxy fatty acids.

Applicants argue that *Arabidopsis* is a model organism to study plant genetics and the oil biosynthetic genes of *Arabidopsis* are similar to those in oil producing crop plants, thus other plants transformed with the kappa hydroxylase gene will also result in the production of triglyceride oil with an altered fatty acid content.

The Examiner maintains the rejection is proper for the reasons set forth in the last office action. As stated above, one example of oil that is derived from transformed seeds of *Arabidopsis* does not define or describe oil that would be derived from any other plant species, given that each plant species differs in the particular combination and expression patterns of oil biosynthetic genes and the availability of precursors for a kappa hydroxylase to act on. One cannot ascertain from the chemical composition of oil from the transformed *Arabidopsis* what the chemical composition of oil would be from any other plant species transformed with a kappa hydroxylase gene or even if any hydroxy fatty acids would be produced in other plant species. In fact, while the example of transformed *Arabidopsis* indicates that *Arabidopsis* can produce hydroxylated fatty acids, one cannot identify a specific chemical composition of oil for *Arabidopsis* transformants given that different transformants of *Arabidopsis* will have different

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levels of expression of the kappa hydroxylase gene, and therefore different compositions of the oil extracted from each. The fact that one plant species has been transformed with a kappa hydroxylase gene and results in the production of hydroxy fatty acids in the seed oil does not enable the production of increased levels of hydroxy fatty acids in any or all other plant species, and it would require undue experimentation by one skilled in the art to test by trial and error the expression of a kappa hydroxylase gene in other plant species and to find which if any other plant species would be capable of producing increased levels of hydroxy fatty acids.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various

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claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 37-41 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Badami et al (Prog. Lipid Res. 19: 119 and 132-136, 1981). Claims 40 and 41 are included in the rejection, given that the claims have not been amended to delete the non-elected plant species.

The claims are drawn to a triglyceride oil characterized by its hydroxy fatty acid content, which is obtained from a plant transformed with a nucleic acid coding for a kappa hydroxylase such that the hydroxy fatty acid of oil from said plant is increased relative to a non-transformed plant. The claims are product-by-process claims.

Badami et al teach seed oils from several plant families that have hydroxy fatty acids, including from the cruciferous species, *Lesquerella*, including ricinoleic, densipolic, lesquerolic, and auricolic fatty acids (see page 132).

The reference teaches a product that appears to be the same as, or an obvious variant of, the product set forth in the product-by-process claim although produced by a different process. See *In re Marosi*, 710 F.2d 799, 218 USPQ 289 (Fed. Cir. 1983) and *In re Thorpe*, 777 F.2d 695, 227 USPQ 964 (Fed. Cir. 1985). See also MPEP § 2113.

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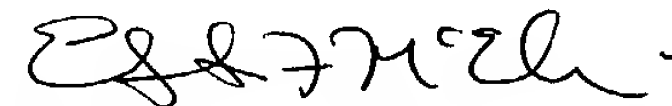
It appears that the claimed seed oil having hydroxy fatty acids is the same as, or an obvious variant of, the seed oil taught by Badami et al that contains hydroxy fatty acids, and the process of making said oil would not impart new characteristics on the oil that would differentiate it from the oil having hydroxy fatty acids that was known and taught in the prior art. Thus the claimed invention would have been prima facie obvious to one of ordinary skill in the art as a whole at the time it was made, if not anticipated by Badami et al.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth F. McElwain whose telephone number is (571) 272-0802. The examiner can normally be reached on increased flex time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (571) 272-0804. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9306 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Elizabeth F. McElwain, Ph.D.
Primary Examiner
Art Unit 1638

EFM
April 16, 2004